

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Applicant: H. William Bosch

Title: NOVEL TRIAMCINOLONE COMPOSITIONS

Appl. No.: 10/697,716

Filing Date: 10/31/2003

Examiner: JEAN-LOUIS, Samira JM

Art Unit: 1617

Confirmation 8372

Number:

REPLY BRIEF

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Sir:

Under the provisions of 37 C.F.R. § 41.39, this Reply Brief is submitted in response to the Examiner's Answer, dated June 23, 2010. Although Appellants believe that no fee is required, authorization is hereby given to charge any deficiency (or credit any balance) to the undersigned deposit account 19-0741.

**REAL PARTY IN INTEREST**

The real party in interest in this appeal is Elan Pharma International Ltd, which is the assignee of the present application as recorded at Reel/Frame numbers 015179/0523.

**RELATED APPEALS AND INTERFERENCES**

No related appeals or interferences are pending.

**STATUS OF CLAIMS**

Claims 1-3, 5-41, 43-108 are pending with claims 8, 15-16, 23-27, and 48-108 withdrawn from examination. Claims 1-3, 5-7, 9-14, 17-22, 28-41, and 43-47 are finally rejected, and are the subject of this appeal. The pending claims are presented in Appendix A of this Brief.

**STATUS OF AMENDMENTS**

As indicated in the final Office Action issued on September 15, 2009, claim amendments made in the Response to the non-final Office Action, filed on July 14, 2009, were entered. No other amendments are pending in the application.

**SUMMARY OF CLAIMED SUBJECT MATTER**

Independent claim 1 is to be argued in the brief. The relevant citation to the specification is shown in the parentheses below.

Independent claim 1 reads as follows:

1. A composition {p. 1, l. 24; p. 16, l. 21} comprising:
  - (a) particles of at least one triamcinolone or a salt thereof {p. 1, ll. 25-26; p. 16, ll. 22-23; p. 18, ll. 8-10}, wherein the triamcinolone particles have an effective average particle size of less than about 2000 nm {p. 1, l. 26 – p. 2, l. 1; p. 16, 26-28; p. 18, ll. 12-13} and have a phase selected from the group consisting of crystalline, amorphous, and semi-crystalline {p. 45, ll. 9-11}; and
  - (b) at least one surface stabilizer adsorbed on the surface of the triamcinolone particles {p. 2, ll. 1-3; p. 16, ll. 24-26; p. 18, ll. 10-11}, wherein said surface stabilizer is a surfactant {p. 46, ll. 11-12}.

**GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

The rejections set forth in the final Office Action dated September 25, 2009 are listed as follows. In the Examiner's Answer, the Examiner indicates that Rejections 16 and 17 have been withdrawn in view of the arguments submitted in the Appeal Brief. Consequently, Rejections 1-15 and 18-21 are to be reviewed on appeal.

1. Provisional rejection of claims 1-3, 5-6 and 14 on the ground of nonstatutory obviousness-type double patenting over claims 51, 60-61 and 64 of copending Application No. 12/320,431 for "Dry Powder Aerosols of Nanoparticulate Drugs".
2. Provisional rejection of claims 1-3, 5, 11-12 and 14 on the ground of nonstatutory obviousness-type double patenting over claims 1-5, 8-10, 15 and 17 of copending Application No. 12/292,092 for "Nanoparticulate Compositions of Immunosuppressive Agents".
3. Provisional rejection of claims 1, 5-7, 10-14, 33-36 and 39-40 on the ground of nonstatutory obviousness-type double patenting over claims 51, 60-61 and 64 of copending Application No. 12/117,982 for "Nanoparticulate Compositions of Angiogenesis Inhibitors" in view of U.S. Patent No. 5,145,684 to Liversidge et al. ("Liversidge").
4. Provisional rejection of claims 1-3, 5-7, 9, 13-14 and 17 on the ground of nonstatutory obviousness-type double patenting over claims 1-17 of copending Application No. 12/052,436 for "Gamma Radiation sterilized Nanoparticulate Docetaxel Compositions and Methods of Making Same".
5. Provisional rejection of claims 1, 5 and 12-14 on the ground of nonstatutory obviousness-type double patenting over claims 10-12 and 19 of copending Application No. 12/051,448 for "Nanoparticulate Compositions of Immunosuppressive Agents".
6. Provisional rejection of claims 1, 5-7, 9-11, 13-14, 21-22, 28-41 and 43 on the ground of nonstatutory obviousness-type double patenting over claims 1, 4-19 and 21-23 of

copending Application No. 11/980,719 for “Nanoparticulate Integrin Antagonist Formulations” in view of Liversidge.

7. Provisional rejection of claims 1, 5-6, 9, 11-14 and 44-47 on the ground of nonstatutory obviousness-type double patenting over claims 1-4, 6, 8, 13-14 and 16-20 of copending Application No. 11/979,253 for “Low Viscosity Liquid Dosage Forms”.

8. Provisional rejection of claims 1, 5-7, 9, 11-14, 20, 28-31, 33-41 and 43 on the ground of nonstatutory obviousness-type double patenting over claims 1-3 and 5-19 of copending Application No. 11/761,900 for “Nanoparticulate Kinase Inhibitor Formulations” in view of Liversidge.

9. Provisional rejection of claims 1, 5-7, 9-11, 13-14, 20-22, 28-32, 33-40 and 43 on the ground of nonstatutory obviousness-type double patenting over claims 1, 4-14, 17-19 and 21-23 of copending Application No. 11/436,887 for “Nanoparticulate Integrin Antagonist Formulations” in view of Liversidge.

10. Provisional rejection of claims 1-2, 5-7, 9-10 and 13-14 on the ground of nonstatutory obviousness-type double patenting over claims 1, 3-5, 9 and 18-21 of copending Application No. 11/376,553 for “Nanoparticulate Leukotriene Receptor Antagonist/Corticosteroid Formulations” in view of Liversidge.

11. Provisional rejection of claims 1, 5-7, 9-14, 18-21, 28-29 and 39-40 on the ground of nonstatutory obviousness-type double patenting over claims 1, 4-6, 8-9, 11-13, 15-16, 18-20, 24 and 27 of copending Application No. 11/275,069 for “Nanoparticulate Compositions of Mitogen-Activated Protein (MAP) Kinase Inhibitors” in view of Liversidge.

12. Provisional rejection of claims 1, 5-7, 9-12, 14, 18-22, 28-29, 31, 33-41 and 43 on the ground of nonstatutory obviousness-type double patenting over claims 1-7, 9-12, 15-17 and

20-31 of copending Application No. 10/912,552 for “Novel Metaxalone Compositions”, now abandoned, in view of Liversidge.

13. Provisional rejection of claims 1, 5-7, 9-14, 18-22, 28-29 and 33-38 on the ground of nonstatutory obviousness-type double patenting over claims 1-10, 12-24, 30, 34-35 and 38-39 of copending Application No. 10/895,405 for “Novel Compositions of Sildenafil Free Base” in view of Liversidge.

14. Provisional rejection of claims 1, 5-7, 9-14, 17-22, 28-41 and 43-47 on the ground of nonstatutory obviousness-type double patenting over claims 1-38 of copending Application No. 10/768,194 for “Novel Fluticasone Formulations”.

15. Provisional rejection of claims 1, 5-7, 9-14, 17-22, 28-41 and 43-47 on the ground of nonstatutory obviousness-type double patenting over claims 1-25 and 36-39 of copending Application No. 10/701,064 for “Novel Glipizide Compositions” in view of Liversidge.

16. (Withdrawn) Provisional rejection of claims 1, 5-7, 9-14, 17-22, 28-41 and 43-47 on the ground of nonstatutory obviousness-type double patenting over claims 1-31, 36-38 and 40 of copending Application No. 10/697,703 for “Novel Nimesulide Compositions”.

17. (Withdrawn) Provisional rejection of claims 1, 5, 9 and 13-14 on the ground of nonstatutory obviousness-type double patenting over claims 1-6 of copending Application No. 10/317,948 for “Pharmaceutical Composition of a Tachykinin Receptor Antagonist”.

18. Provisional rejection of claims 1, 5-7, 9-14, 18-22, 28-29 and 33-40 on the ground of nonstatutory obviousness-type double patenting over claims 1, 4-19 and 21-32 of copending Application No. 11/928,250 for “Nanoparticulate Compositions of Angiogenesis Inhibitors” in view of Liversidge.

19. Provisional rejection of claims 1, 5-7, 9-14, 28-29, 33-41 and 43 on the ground of nonstatutory obviousness-type double patenting over claims 1, 4-19 and 21-32 of copending Application No. 11/367,716 for “Nanoparticulate Statin Formulations and Novel Statin Combinations” in view of Liversidge.

20. Provisional rejection of claims 1, 5-7, 9-14, 17-22 and 33-36 on the ground of nonstatutory obviousness-type double patenting over claims 1-6 of copending Application No. 10/784,900 for “Nanoparticulate Meloxicam Formulations”.

21. Rejection of claims 1-3, 5-7, 9-14, 17-22, 28-41 and 43-47 under 35 U.S.C. §103(a) for allegedly being obvious over Liversidge in view of U.S. Patent No. 5,916,596 to Desai et al. (“Desai”).

**ARGUMENT**

**I. Rejection No. 12 is Moot**

As noted above, Application No. 10/912,552 for “Novel Metaxalone Compositions” is abandoned. Thus, Rejection No. 12, in which claims 1, 5-7, 9-12, 14, 18-22, 28-29, 31, 33-41 and 43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-7, 9-12, 15-17 and 20-31 of copending Application No. 10/912,552 in view of Liversidge, is moot.

In the Answer, the Examiner is silent as to Appellants’ arguments regarding Rejections 1-11, 13-15, and 18-20 submitted in the Appeal Brief. These arguments are incorporated by reference in this Reply Brief.

**II. The Examiner’s Comments Regarding Rejection 21**

Pursuant to 37 C.F.R. §41.39, Appellants respond to certain comments made in the Examiner’s Answer dated June 23, 2010 (“the Answer”). The Examiner specifically commented on Appellants’ rebuttal for Rejection 21, in which claims 1-3, 5-7, 9-14, 17-22, 28-41 and 43-47 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over Liversidge in view of Desai.

**A. A reasonable expectation of success is lacking.**

According to the Examiner, “one of ordinary skill in the art would have indeed found it obvious to substitute and obvious to try triamcinolone in the composition of Liversidge” because Liversidge teaches the genus of poorly water soluble drugs and Desai teaches that triamcinolone is a poorly water soluble drug. *See* the Answer, the paragraph bridging pages 10 and 11.

As discussed in detail in the Appeal Brief and incorporated herewith by reference, the prior-art disclosure of a genus of poorly water soluble drugs does not render the claimed species

of triamcinolone obvious. *See* Appeal Brief, pages 17-19. In the Answer, the Examiner is silent as to Appellants' analysis of the cited art and the guidelines set forth by MPEP 2144.08. Rather, the Examiner emphasized that it is obvious to substitute or obvious to try the active agents disclosed by Desai. However, the Examination Guidelines for Determining Obviousness under 35 U.S.C. § 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.* ("the Guidelines," Federal Register Vol. 72, No. 195, 57526-57535 (2007)) requires that the rationales of "simple substitution" or "obvious to try" be supported by a finding that the results of the substitution would have been predictable or by a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success. A predictable result or a reasonable expectation of success is lacking in view of Liversidge's express teaching that not every combination of active agent and surface stabilizer can result in a stable nanoparticulate active agent composition.

The Examiner disregards Appellants' arguments in the Appeal Brief and maintains the self-serving conclusion that one of ordinary skill in the art would have a reasonable expectation of success in the absence of any factual support.

**B. Attempting each of numerous choices is an improper obvious-to-try rationale.**

Moreover, the Examiner contends that in view of KSR, "one of ordinary skill in the art would have found it obvious to try each and every drug disclosed by Desai" (the Answer, page 11, lines 2-4). This rationale is defective in at least two aspects.

First, the primary reference, Liversidge, does not have any suggestion that a corticosteroid, such as triamcinolone, is preferred over other drugs. In view of an enormous number of poorly water soluble drugs available to date, the Examiner could have only selected Desai as the secondary reference informed by Appellants' claimed invention. In other words, if the claimed invention were directed to another active agent, the Examiner would have selected a different secondary reference.

Second, a suggestion to try each species of the genus or subgenus is explicitly rejected as a proper application of “obvious to try” rationale in the recent Federal Circuit ruling, excerpted below:

*To differentiate between proper and improper applications of “obvious to try,” this court outlined two classes of situations where “obvious to try” is erroneously equated with obviousness under §103. In the first class of cases, what would have been “obvious to try” would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.*

*In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009) (citing *In re O’Farrell*, 853 F.2d 894 (Fed. Cir. 1988); (emphasis added). *Kubin* further analogizes this rejection rationale with “throw[ing] metaphorical darts at a board filled with combinatorial prior art possibilities” with the aid of hindsight, and therefore, is improper. *Id.*

**C. The Examiner has not established that the cited art discloses a finite number of predictable solutions.**

Furthermore, the Examiner contends that “a finite number of predictable solutions was indeed provided by the prior art,” and that [t]he fact that a long list of possible drugs to be incorporated into the compositions was provided does not preclude one skilled in the art to try each and every single possibility purported by the prior art....” The Answer, the paragraph bridging pages 11 and 12.

As discussed above and in the Appeal Brief, Liversidge discloses over 40 categories of drugs, each of which encompasses many members. There is no teaching or suggestion in Liversidge that a stable nanoparticulate active agent composition can be made for each species encompassed by the genus. Therefore, the Examiner’s assertion that prior art teaches “a finite number of predictable solutions” lacks valid support in the art.

Similar to the discussion in Section B, trying each and every single possibility is an improper obvious-to-try rationale explicitly rejected by the Federal Circuit.

In view of the foregoing, Appellants respectfully request that the Board reverse the rejection in whole.

**CONCLUSION**

For the reasons discussed above, Appellants respectfully submit that all pending claims are in condition for allowance, and respectfully requests that the rejections be reversed in whole, and that the claims be allowed to issue.

Respectfully submitted,

By 

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**APPENDIX A: CLAIMS INVOLVED IN APPEAL**

1. (Previously Presented) A composition comprising:
  - (a) particles of at least one triamcinolone or a salt thereof, wherein the triamcinolone particles have an effective average particle size of less than about 2000 nm and have a phase selected from the group consisting of crystalline, amorphous, and semi-crystalline; and
  - (b) at least one surface stabilizer adsorbed on the surface of the triamcinolone particles, wherein said surface stabilizer is a surfactant.
2. (Original) The composition of claim 1, wherein the triamcinolone is selected from the group consisting of triamcinolone, triamcinolone acetonide, triamcinolone diacetate, triamcinolone hexacetonide, and triamcinolone benetonide.
3. (Original) The composition of claim 2, wherein the triamcinolone is triamcinolone acetonide.
4. (Cancelled)
5. (Original) The composition of claim 1, wherein the effective average particle size of the triamcinolone particles is selected from the group consisting of less than about 1900 nm, less than about 1800 nm, less than about 1700 nm, less than about 1600 nm, less than about 1500 nm, less than about 1400 nm, less than about 1300 nm, less than about 1200 nm, less than about 1100 nm, less than about 1000 nm, less than about 900 nm, less than about 800 nm, less than about 700 nm, less than about 600 nm, less than about 500 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.
6. (Original) The composition of claim 1, wherein the composition is formulated for administration selected from the group consisting of oral, pulmonary, rectal, ophthalmic, colonic,

parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.

7. (Original) The composition of claim 1 formulated into a dosage form selected from the group consisting of liquid dispersions, sachets, lozenges, oral suspensions, gels, aerosols, ointments, creams, tablets, capsules, and powders.

8. (Withdrawn) The composition of claim 1 formulated into a dosage form selected from the group consisting of controlled release formulations, fast melt formulations, lyophilized formulations, delayed release formulations, extended release formulations, pulsatile release formulations, and mixed immediate release and controlled release formulations.

9. (Original) The composition of claim 1, wherein the composition further comprises one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.

10. (Original) The composition of claim 1, wherein the triamcinolone or a salt thereof is present in an amount selected from the group consisting of from about 99.5% to about 0.001%, from about 95% to about 0.1%, and from about 90% to about 0.5%, by weight, based on the total combined dry weight of the triamcinolone or salt thereof and at least one surface stabilizer, not including other excipients.

11. (Original) The composition of claim 1, wherein the at least one surface stabilizer is present in an amount selected from the group consisting of from about 0.5% to about 99.999% by weight, from about 5.0% to about 99.9% by weight, and from about 10% to about 99.5% by weight, based on the total combined dry weight of the triamcinolone or salt thereof and at least one surface stabilizer, not including other excipients.

12. (Original) The composition of claim 1, comprising at least two surface stabilizers.

13. (Previously Presented) The composition of claim 1, wherein the surface stabilizer is selected from the group consisting of a nonionic surface stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, and a zwitterionic surface stabilizer.

14. (Previously Presented) The composition of claim 13, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oils, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isonylphenoxy poly-(glycidol), decanoyl-N-methylglucamide; n-decyl  $\beta$ -D-glucopyranoside; n-decyl  $\beta$ -D-maltopyranoside; n-dodecyl  $\beta$ -D-glucopyranoside; n-dodecyl  $\beta$ -D-maltoside; heptanoyl-N-methylglucamide; n-heptyl- $\beta$ -D-glucopyranoside; n-heptyl  $\beta$ -D-thioglucoside; n-hexyl  $\beta$ -D-glucopyranoside; nonanoyl-N-methylglucamide; n-noyl  $\beta$ -D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl- $\beta$ -D-glucopyranoside; octyl  $\beta$ -D-thioglucopyranoside; lysozyme, PEG-phospholipid, PEG-cholesterols, PEG-vitamin A, and random copolymers of vinyl acetate and vinyl pyrrolidone.

15. (Withdrawn) The composition of claim 13, whercin the at least one cationic surface stabilizer is selected from the group consisting of a polymer, a biopolymer, a polysaccharide, a cellulosic, an alginate, a nonpolymeric compound, and a phospholipid.

16. (Withdrawn) The composition of claim 13, wherein the surface stabilizer is selected from the group consisting of cationic lipids, polymethylmethacrylate trimethylammonium bromide, sulfonium compounds, polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, hexadecyltrimethyl ammonium bromide, phosphonium compounds, quarternary ammonium compounds, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride bromide, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride bromide, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium chloride, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium bromide, N-alkyl (C<sub>12-18</sub>)dimethylbenzyl ammonium chloride, N-alkyl (C<sub>14-18</sub>)dimethyl-benzyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C<sub>12</sub> trimethyl ammonium bromides, C<sub>15</sub> trimethyl ammonium bromides, C<sub>17</sub> trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides,

alkyldimethylammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, polyquaternium 10, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, quaternized ammonium salt polymers, alkyl pyridinium salts; amines, amine salts, amine oxides, imide azolinium salts, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

17. (Original) The composition of claim 1, comprising as a surface stabilizer a random copolymer of vinyl pyrrolidone and vinyl acetate, sodium lauryl sulfate, lysozyme, tyloxapol, or a combination thereof.

18. (Previously Presented) The composition of claim 13, wherein the composition is bioadhesive.

19. (Original) The composition of claim 1, further comprising at least one additional triamcinolone composition having an effective average particle size which is different than the effective average particle size of the triamcinolone composition of claim 1.

20. (Original) The composition of claim 1, additionally comprising one or more non-triamcinolone active agents.

21. (Original) The composition of claim 20, wherein said additional one or more non-triamcinolone active agents are selected from the group consisting of nutraceuticals, amino acids, proteins, peptides, nucleotides, anti-obesity drugs, central nervous system stimulants, carotenoids, corticosteroids, elastase inhibitors, anti-fungals, oncology therapies, anti-emetics, analgesics, cardiovascular agents, anti-inflammatory agents, anthelmintics, anti-arrhythmic agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics,

antihistamines, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, immunosuppressants, antithyroid agents, antiviral agents, anxiolytics, sedatives, astringents, alpha-adrenergic receptor blocking agents, beta-adrenoceptor blocking agents, blood products, blood substitutes, cardiac inotropic agents, contrast media, corticosteroids, cough suppressants, decongestants, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics, immunological agents, lipid regulating agents, muscle relaxants, parasympathomimetics, parathyroid calcitonin, parathyroid biphosphonates, prostaglandins, radio-pharmaceuticals, sex hormones, anti-allergic agents, stimulants, anorectics, sympathomimetics, thyroid agents, vasodilators, and xanthines.

22. (Original) The composition of claim 20, wherein said additional one or more non-triamcinolone active agents are selected from the group consisting of acyclovir, alprazolam, altretamine, amiloride, amiodarone, benztropine mesylate, bupropion, cabergoline, candesartan, cerivastatin, chlorpromazine, ciprofloxacin, cisapride, clarithromycin, clonidine, clopidogrel, cyclobenzaprine, cyproheptadine, delavirdine, desmopressin, diltiazem, dipyridamole, dolasetron, enalapril maleate, enalaprilat, famotidine, felodipine, furazolidone, glipizide, irbesartan, ketoconazole, lansoprazole, loratadine, loxapine, mebendazole, mercaptopurine, milrinone lactate, minocycline, mitoxantrone, nelfinavir mesylate, nimodipine, norfloxacin, olanzapine, omeprazole, penciclovir, pimozide, tacolimus, quazepam, raloxifene, rifabutin, rifampin, risperidone, rizatriptan, saquinavir, sertraline, sildenafil, acetyl-sulfisoxazole, temazepam, thiabendazole, thioguanine, trandolapril, triamterene, trimetrexate, troglitazone, trovafloxacin, verapamil, vinblastine sulfate, mycophenolate, atovaquone, atovaquone, proguanil, ceftazidime, cefuroxime, etoposide, terbinafine, thalidomide, fluconazole, amsacrine, dacarbazine, teniposide, and acetylsalicylate.

23. (Withdrawn) The composition of claim 20, further comprising at least one antihistamine, decongestant, bronchodilator, anti-fungal, anti-cancer agent, or immunosuppressant.

24. (Withdrawn) The composition of claim 23, wherein the antihistamine is selected from the group consisting of fexofenadine, azelastine, hydroxyzine, diphenhydramine, loratadine, chlorpheniramine maleate, ciproheptadine, promethazine, phenylephrine tannate, acrivastine, and cetirizine.

25. (Withdrawn) The composition of claim 23, wherein the decongestant is selected from the group consisting of pseudoephedrine, oxymetazoline, xylometazoline, naphazoline, naphazoline, and tetrahydrozoline.

26. (Withdrawn) The composition of claim 23, wherein the bronchodilator is selected from the group consisting of short-acting beta2-agonists, long-acting beta2-agonists, anticholinergics, and theophyllines.

27. (Withdrawn) The composition of claim 23, wherein the anti-fungal agent is selected from the group consisting of amphotericin B, nystatin, fluconazole, ketoconazole, terbinafine, itraconazole, imidazole, triazole, ciclopirox, clotrimazole, and miconazole.

28. (Original) The composition of claim 1, wherein upon administration to a mammal the triamcinolone particles redisperse such that the particles have an effective average particle size of less than about 2 microns.

29. (Original) The composition of claim 28, wherein upon administration the composition redisperses such that the triamcinolone particles have an effective average particle size selected from the group consisting of less than about 1900 nm, less than about 1800 nm, less than about 1700 nm, less than about 1600 nm, less than about 1500 nm, less than about 1400 nm, less than about 1300 nm, less than about 1200 nm, less than about 1100 nm, less than about 1000 nm, less than about 900 nm, less than about 800 nm, less than about 700 nm, less than about 600 nm, less than about 500 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 150 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

30. (Original) The composition of claim 1, wherein the composition redisperses in a biorelevant media such that the triamcinolone particles have an effective average particle size of less than about 2 microns.

31. (Original) The composition of claim 30, wherein the biorelevant media is selected from the group consisting of water, aqueous electrolyte solutions, aqueous solutions of a salt, aqueous solutions of an acid, aqueous solutions of a base, and combinations thereof.

32. (Original) The composition of claim 30, wherein the composition redisperses in a biorelevant media such that the triamcinolone particles have an effective average particle size selected from the group consisting of less than about 1900 nm, less than about 1800 nm, less than about 1700 nm, less than about 1600 nm, less than about 1500 nm, less than about 1400 nm, less than about 1300 nm, less than about 1200 nm, less than about 1100 nm, less than about 1000 nm, less than about 900 nm, less than about 800 nm, less than about 700 nm, less than about 600 nm, less than about 500 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 150 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

33. (Original) The composition of claim 1, wherein the  $T_{max}$  of the triamcinolone composition, when assayed in the plasma of a mammalian subject following administration, is less than the  $T_{max}$  exhibited by a non-nanoparticulate composition of the same triamcinolone, administered at the same dosage.

34. (Original) The composition of claim 33, wherein the  $T_{max}$  is selected from the group consisting of not greater than about 90%, not greater than about 80%, not greater than about 70%, not greater than about 60%, not greater than about 50%, not greater than about 30%, not greater than about 25%, not greater than about 20%, not greater than about 15%, not greater than about 10%, and not greater than about 5% of the  $T_{max}$  exhibited by a non-nanoparticulate composition of the same triamcinolone, administered at the same dosage.

35. (Original) The composition of claim 1, wherein the  $C_{max}$  of the triamcinolone composition, when assayed in the plasma of a mammalian subject following administration, is greater than the  $C_{max}$  exhibited by a non-nanoparticulate composition of the same triamcinolone, administered at the same dosage.

36. (Original) The composition of claim 35, wherein the  $C_{max}$  is selected from the group consisting of at least about 50%, at least about 100%, at least about 200%, at least about 300%, at least about 400%, at least about 500%, at least about 600%, at least about 700%, at least about 800%, at least about 900%, at least about 1000%, at least about 1100%, at least about 1200%, at least about 1300%, at least about 1400%, at least about 1500%, at least about 1600%, at least about 1700%, at least about 1800%, or at least about 1900% greater than the  $C_{max}$  exhibited by a non-nanoparticulate composition of the same triamcinolone, administered at the same dosage.

37. (Original) The composition of claim 1, wherein the AUC of the triamcinolone composition, when assayed in the plasma of a mammalian subject following administration, is greater than the AUC exhibited by a non-nanoparticulate composition of the same triamcinolone, administered at the same dosage.

38. (Original) The composition of claim 37, wherein the AUC is selected from the group consisting of at least about 25%, at least about 50%, at least about 75%, at least about 100%, at least about 125%, at least about 150%, at least about 175%, at least about 200%, at least about 225%, at least about 250%, at least about 275%, at least about 300%, at least about 350%, at least about 400%, at least about 450%, at least about 500%, at least about 550%, at least about 600%, at least about 750%, at least about 700%, at least about 750%, at least about 800%, at least about 850%, at least about 900%, at least about 950%, at least about 1000%, at least about 1050%, at least about 1100%, at least about 1150%, or at least about 1200% greater than the AUC exhibited by a non-nanoparticulate composition of the same triamcinolone, administered at the same dosage.

39. (Previously Presented) The composition of claim 1, wherein when the composition is administered to a subject under fed conditions, the absorption levels of the at least one triamcinolone are substantially the same as compared to when the composition is administered to a patient under fasting conditions.

40. (Original) The composition of claim 39, wherein the difference in absorption of the triamcinolone composition of the invention, when administered in the fed versus the fasted state, is selected from the group consisting of less than about 100%, less than about 90%, less than about 80%, less than about 70%, less than about 60%, less than about 50%, less than about 40%, less than about 30%, less than about 25%, less than about 20%, less than about 15%, less than about 10%, less than about 5%, and less than about 3%.

41. (Previously Presented) The composition of claim 1, wherein administration of the composition to a subject in a fasted state is bioequivalent to administration of the composition in a fed state, wherein bioequivalency is established by a 90% Confidence Interval of between 0.80 and 1.25 for AUC and a 90% Confidence Interval of between 0.7 to 1.43 for  $C_{max}$ .

42. (Cancelled)

43. (Previously Presented) The composition of claim 41, wherein bioequivalency is established by a 90% confidence Interval of between 0.80 and 1.25 for AUC and a 90% confidence Interval of between 0.70 to 1.43 for  $C_{max}$ .

44. (Original) The composition of claim 1 formulated into a liquid dosage form, wherein the dosage form has a viscosity of less than about 2000 mPa·s, measured at 20°C, at a shear rate of 0.1 (1/s).

45. (Original) The composition of claim 44, having a viscosity at a shear rate of 0.1 (1/s), measured at 20°C, selected from the group consisting of from about 2000 mPa·s to about 1 mPa·s, from about 1900 mPa·s to about 1 mPa·s, from about 1800 mPa·s to about 1 mPa·s, from

about 1700 mPa·s to about 1 mPa·s, from about 1600 mPa·s to about 1 mPa·s, from about 1500 mPa·s to about 1 mPa·s, from about 1400 mPa·s to about 1 mPa·s, from about 1300 mPa·s to about 1 mPa·s, from about 1200 mPa·s to about 1 mPa·s, from about 1100 mPa·s to about 1 mPa·s, from about 1000 mPa·s to about 1 mPa·s, from about 900 mPa·s to about 1 mPa·s, from about 800 mPa·s to about 1 mPa·s, from about 700 mPa·s to about 1 mPa·s, from about 600 mPa·s to about 1 mPa·s, from about 500 mPa·s to about 1 mPa·s, from about 400 mPa·s to about 1 mPa·s, from about 300 mPa·s to about 1 mPa·s, from about 200 mPa·s to about 1 mPa·s, from about 175 mPa·s to about 1 mPa·s, from about 150 mPa·s to about 1 mPa·s, from about 125 mPa·s to about 1 mPa·s, from about 100 mPa·s to about 1 mPa·s, from about 75 mPa·s to about 1 mPa·s, from about 50 mPa·s to about 1 mPa·s, from about 25 mPa·s to about 1 mPa·s, from about 15 mPa·s to about 1 mPa·s, from about 10 mPa·s to about 1 mPa·s, and from about 5 mPa·s to about 1 mPa·s.

46. (Original) The composition of claim 44, wherein the viscosity of the dosage form is selected from the group consisting of less than about 1/200, less than about 1/100, less than about 1/50, less than about 1/25, and less than about 1/10 of the viscosity of a liquid dosage form of a non-nanoparticulate composition of the same triamcinolone, at about the same concentration per ml of triamcinolone.

47. (Original) The composition of claim 44, wherein the viscosity of the dosage form is selected from the group consisting of less than about 5%, less than about 10%, less than about 15%, less than about 20%, less than about 25%, less than about 30%, less than about 35%, less than about 40%, less than about 45%, less than about 50%, less than about 55%, less than about 60%, less than about 65%, less than about 70%, less than about 75%, less than about 80%, less than about 85%, and less than about 90% of the viscosity of a liquid dosage form of a non-nanoparticulate composition of the same triamcinolone, at about the same concentration per ml of triamcinolone.

48. (Withdrawn) A method of making a triamcinolone composition comprising contacting particles of a triamcinolone or a salt thereof with at least one surface stabilizer for a time and under conditions sufficient to provide a triamcinolone composition having an effective average particle size of less than about 2000 nm.

49. (Withdrawn) The method of claim 48, wherein the triamcinolone is selected from the group consisting of triamcinolone, triamcinolone acetonide, triamcinolone diacetate, triamcinolone hexacetonide, and triamcinolone benetonide.

50. (Withdrawn) The method of claim 49, wherein the triamcinolone is triamcinolone acetonide.

51. (Withdrawn) The method of claim 48, wherein said contacting comprises grinding.

52. (Withdrawn) The method of claim 51, wherein said grinding comprises wet grinding.

53. (Withdrawn) The method of claim 48, wherein said contacting comprises homogenizing.

54. (Withdrawn) The method of claim 48, wherein said contacting comprises:

- (a) dissolving the particles of a triamcinolone or salt thereof in a solvent;
- (b) adding the resulting triamcinolone solution to a solution comprising at least one surface stabilizer; and
- (c) precipitating the solubilized triamcinolone/surface stabilizer composition by the addition of a non-solvent.

55. (Withdrawn) The method of claim 48, wherein the triamcinolone or salt thereof is selected from the group consisting of a crystalline phase, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, and mixtures thereof.

56. (Withdrawn) The method of claim 48, wherein the effective average particle size of the triamcinolone particles is selected from the group consisting of less than about 1900 nm, less than about 1800 nm, less than about 1700 nm, less than about 1600 nm, less than about 1500 nm, less than about 1000 nm, less than about 1400 nm, less than about 1300 nm, less than about 1200 nm, less than about 1100 nm, less than about 900 nm, less than about 800 nm, less than about 700 nm, less than about 600 nm, less than about 500 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

57. (Withdrawn) The method of claim 48, wherein the triamcinolone or salt thereof is present in an amount selected from the group consisting of from about 99.5% to about 0.001%, from about 95% to about 0.1%, and from about 90% to about 0.5%, by weight, based on the total combined dry weight of the triamcinolone or a salt thereof and at least one surface stabilizer, not including other excipients.

58. (Withdrawn) The method of claim 48, wherein the at least one surface stabilizer is present in an amount selected from the group consisting of from about 0.5% to about 99.999%, from about 5.0% to about 99.9%, and from about 10% to about 99.5% by weight, based on the total combined dry weight of the triamcinolone or a salt thereof and at least one surface stabilizer, not including other excipients.

59. (Withdrawn) The method of claim 48, utilizing at least two surface stabilizers.

60. (Withdrawn) The method of claim 48, wherein the surface stabilizer is selected from the group consisting of a nonionic surface stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, a zwitterionic surface stabilizer, and an ionic surface stabilizer.

61. (Withdrawn) The method of claim 60, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oils, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isonylphenoxy poly-(glycidol), decanoyl-N-methylglucamide; n-decyl  $\beta$ -D-glucopyranoside; n-decyl  $\beta$ -D-maltopyranoside; n-dodecyl  $\beta$ -D-glucopyranoside; n-dodecyl  $\beta$ -D-maltoside; heptanoyl-N-methylglucamide; n-heptyl- $\beta$ -D-glucopyranoside; n-heptyl  $\beta$ -D-thioglucoside; n-hexyl  $\beta$ -D-glucopyranoside; nonanoyl-N-methylglucamide; n-noyl  $\beta$ -D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl- $\beta$ -D-glucopyranoside; octyl  $\beta$ -D-thioglucopyranoside; lysozyme, PEG-phospholipid, PEG-cholesterols, PEG-vitamin A, PEG-vitamin E, and random copolymers of vinyl acetate and vinyl pyrrolidone.

62. (Withdrawn) The method of claim 60, wherein the at least one cationic surface stabilizer is selected from the group consisting of a polymer, a biopolymer, a polysaccharide, a cellulosic, an alginate, a nonpolymeric compound, and a phospholipid.

63. (Withdrawn) The method of claim 60, wherein the surface stabilizer is selected from the group consisting of cationic lipids, polymethylmethacrylate trimethylammonium

bromide, sulfonium compounds, polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, hexadecyltrimethyl ammonium bromide, phosphonium compounds, quarternary ammonium compounds, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride bromide, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium chloride, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium bromide, N-alkyl (C<sub>12-18</sub>)dimethylbenzyl ammonium chloride, N-alkyl (C<sub>14-18</sub>)dimethyl-benzyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C<sub>12</sub> trimethyl ammonium bromides, C<sub>15</sub> trimethyl ammonium bromides, C<sub>17</sub> trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkylidimethylammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, polyquaternium 10,

tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, quaternized ammonium salt polymers, alkyl pyridinium salts; amines, amine salts, amine oxides, imide azolinium salts, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

64. (Withdrawn) The composition of claim 1, comprising as a surface stabilizer a random copolymer of vinyl pyrrolidone and vinyl acetate, sodium lauryl sulfate, lysozyme, tyloxapol, or a combination thereof.

65. (Withdrawn) The method of claim 60, wherein the composition is bioadhesive.

66. (Withdrawn) A method of treating a subject in need comprising administering to the subject an effective amount of a composition comprising:

(a) particles of a triamcinolone or a salt thereof, wherein the triamcinolone particles have an effective average particle size of less than about 2000 nm; and  
(b) at least one surface stabilizer.

67. (Withdrawn) The method of claim 66, wherein the triamcinolone is selected from the group consisting of triamcinolone, triamcinolone acetonide, triamcinolone diacetate, triamcinolone hexacetonide, and triamcinolone benetonide.

68. (Withdrawn) The method of claim 67, wherein the triamcinolone is triamcinolone acetonide.

69. (Withdrawn) The method of claim 66, wherein the triamcinolone or a salt thereof is selected from the group consisting of a crystalline phase, an amorphous phase, a semi-crystalline phase, a semi-amorphous phase, and mixtures thereof.

70. (Withdrawn) The method of claim 66, wherein the effective average particle size of the triamcinolone particles is selected from the group consisting of less than about 1900 nm, less than about 1800 nm, less than about 1700 nm, less than about 1600 nm, less than about 1500 nm, less than about 1400 nm, less than about 1300 nm, less than about 1200 nm, less than about 1100 nm, less than about 1000 nm, less than about 900 nm, less than about 800 nm, less than about 700 nm, less than about 600 nm, less than about 500 nm, less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 200 nm, less than about 100 nm, less than about 75 nm, and less than about 50 nm.

71. (Withdrawn) The method of claim 66, wherein the composition is formulated for administration selected from the group consisting of oral, pulmonary, rectal, ophthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.

72. (Withdrawn) The method of claim 66, wherein the composition further comprises one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.

73. (Withdrawn) The method of claim 66, wherein the triamcinolone or salt thereof is present in an amount selected from the group consisting of from about 99.5% to about 0.001%, from about 95% to about 0.1%, and from about 90% to about 0.5%, by weight, based on the total combined dry weight of the triamcinolone or salt thereof and at least one surface stabilizer, not including other excipients.

74. (Withdrawn) The method of claim 66, wherein the at least one surface stabilizer is present in an amount selected from the group consisting of from about 0.5% to about 99.999% by weight, from about 5.0% to about 99.9% by weight, and from about 10% to about 99.5% by weight, based on the total combined dry weight of the triamcinolone or a salt thereof and at least one surface stabilizer, not including other excipients.

75. (Withdrawn) The method of claim 66, utilizing at least two surface stabilizers.

76. (Withdrawn) The method of claim 66, wherein at least one surface stabilizer is selected from the group consisting of a nonionic surface stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, a zwitterionic surface stabilizer, and an ionic surface stabilizer.

77. (Withdrawn) The method of claim 76, wherein at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oils, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isonylphenoxyxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl  $\beta$ -D-glucopyranoside; n-decyl  $\beta$ -D-maltopyranoside; n-dodecyl  $\beta$ -D-glucopyranoside; n-dodecyl  $\beta$ -D-maltoside; heptanoyl-N-methylglucamide; n-heptyl- $\beta$ -D-glucopyranoside; n-heptyl  $\beta$ -D-thioglucoside; n-hexyl  $\beta$ -D-glucopyranoside; nonanoyl-N-methylglucamide; n-noyl  $\beta$ -D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl- $\beta$ -D-glucopyranoside; octyl  $\beta$ -D-thioglucopyranoside; lysozyme, PEG-phospholipid, PEG-cholesterols, PEG-vitamin A, PEG-vitamin E, and random copolymers of vinyl acetate and vinyl pyrrolidone.

78. (Withdrawn) The method of claim 76, wherein at least one cationic surface stabilizer is selected from the group consisting of a polymer, a biopolymer, a polysaccharide, a cellulosic, an alginate, a nonpolymeric compound, and a phospholipid.

79. (Withdrawn) The method of claim 76, wherein the surface stabilizer is selected from the group consisting of benzalkonium chloride, polymethylmethacrylate trimethylammonium bromide, polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, hexadecyltrimethyl ammonium bromide, cationic lipids, sulfonium compounds, phosphonium compounds, quarternary ammonium compounds, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride bromide, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium chloride, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium bromide, N-alkyl (C<sub>12-18</sub>)dimethylbenzyl ammonium chloride, N-alkyl (C<sub>14-18</sub>)dimethyl-benzyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl

ammonium bromide, C<sub>12</sub> trimethyl ammonium bromides, C<sub>15</sub> trimethyl ammonium bromides, C<sub>17</sub> trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyldimethylammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, polyquaternium 10, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, quaternized ammonium salt polymers, alkyl pyridinium salts; amines, amine salts, amine oxides, imide azolinium salts, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

80. (Withdrawn) The method of claim 66, comprising as a surface stabilizer a random copolymer of vinyl pyrrolidone and vinyl acetate, sodium lauryl sulfate, lysozyme, tyloxapol, or a combination thereof.

81. (Withdrawn) The method of claim 76, wherein the composition is bioadhesive.

82. (Withdrawn) The method of claim 66, additionally comprising administering one or more non-triamcinolone active agents.

83. (Withdrawn) The method of claim 82, wherein said additional one or more non-triamcinolone active agents are selected from the group consisting of nutraceuticals, amino acids, proteins, peptides, nucleotides, anti-obesity drugs, central nervous system stimulants, carotenoids, corticosteroids, elastase inhibitors, anti-fungals, oncology therapies, anti-emetics, analgesics, cardiovascular agents, anti-inflammatory agents, anthelmintics, anti-arrhythmic agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antihypertensive agents, antimuscarinic agents, antimycobacterial agents,

antineoplastic agents, immunosuppressants, antithyroid agents, antiviral agents, anxiolytics, sedatives, astringents, alpha-adrenergic receptor blocking agents, beta-adrenoceptor blocking agents, blood products, blood substitutes, cardiac inotropic agents, contrast media, corticosteroids, cough suppressants, diagnostic agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics, immunological agents, lipid regulating agents, muscle relaxants, parasympathomimetics, parathyroid calcitonin, parathyroid biphosphonates, prostaglandins, radio-pharmaceuticals, sex hormones, anti-allergic agents, stimulants, anoretics, sympathomimetics, thyroid agents, vasodilators, and xanthines.

84. (Withdrawn) The method of claim 82, wherein said additional one or more non-triamcinolone active agents are selected from the group consisting of acyclovir, alprazolam, altretamine, amiloride, amiodarone, benztropine mesylate, bupropion, cabergoline, candesartan, cerivastatin, chlorpromazine, ciprofloxacin, cisapride, clarithromycin, clonidine, clopidogrel, cyclobenzaprine, cyproheptadine, delavirdine, desmopressin, diltiazem, dipyridamole, dolasetron, enalapril maleate, enalaprilat, famotidine, felodipine, furazolidone, glipizide, irbesartan, ketoconazole, lansoprazole, loratadine, loxapine, mebendazole, mercaptopurine, milrinone lactate, minocycline, mitoxantrone, nelfinavir mesylate, nimodipine, norfloxacin, olanzapine, omeprazole, penciclovir, pimozide, tacolimus, quazepam, raloxifene, rifabutin, rifampin, risperidone, rizatriptan, saquinavir, sertraline, sildenafil, acetyl-sulfisoxazole, temazepam, thiabendazole, thioguanine, trandolapril, triamterene, trimetrexate, troglitazone, trovafloxacin, verapamil, vinblastine sulfate, mycophenolate, atovaquone, atovaquone, proguanil, ceftazidime, cefuroxime, etoposide, terbinafine, thalidomide, fluconazole, amsacrine, dacarbazine, teniposide, and acetylsalicylate.

85. (Withdrawn) The method of claim 82, further comprising administering at least one antihistamine, decongestant, bronchodilator, anti-fungal, anti-cancer agent, or immunosuppressant.

86. (Withdrawn) The method of claim 85, wherein the antihistamine is selected from the group consisting of fexofenadine, azelastine, hydroxyzine, diphenhydramine, loratadine, chlorpheniramine maleate, cyproheptadine, promethazine, phenylephrine tannate, acrivastine, and cetirizine.

87. (Withdrawn) The method of claim 85, wherein the decongestant is selected from the group consisting of pseudoephedrine, oxymetazoline, xylometazoline, naphazoline, naphazoline, and tetrahydrozoline.

88. (Withdrawn) The method of claim 85, wherein the bronchodilator is selected from the group consisting of short-acting beta<sub>2</sub>-agonists, long-acting beta<sub>2</sub>-agonists, anticholinergics, and theophyllines.

89. (Withdrawn) The method of claim 85, wherein the anti-fungal agent is selected from the group consisting of amphotericin B, nystatin, fluconazole, ketoconazole, terbinafine, itraconazole, imidazole, triazole, ciclopirox, clotrimazole, and miconazole.

90. (Withdrawn) The method of claim 66, wherein the T<sub>max</sub> of the triamcinolone composition, when assayed in the plasma of a mammalian subject following administration, is less than the T<sub>max</sub> for a non-nanoparticulate composition of the same triamcinolone, administered at the same dosage.

91. (Withdrawn) The method of claim 90, wherein the T<sub>max</sub> is selected from the group consisting of not greater than about 90%, not greater than about 80%, not greater than about 70%, not greater than about 60%, not greater than about 50%, not greater than about 30%, not greater than about 25%, not greater than about 20%, not greater than about 15%, not greater than about 10%, and not greater than about 5% of the T<sub>max</sub> exhibited by the non-nanoparticulate composition of the same triamcinolone, administered at the same dosage.

92. (Withdrawn) The method of claim 66, wherein the  $C_{max}$  of the triamcinolone composition, when assayed in the plasma of a mammalian subject following administration, is greater than the  $C_{max}$  for a non-nanoparticulate composition of the same triamcinolone, administered at the same dosage.

93. (Withdrawn) The method of claim 92, wherein the  $C_{max}$  is selected from the group consisting of at least about 50%, at least about 100%, at least about 200%, at least about 300%, at least about 400%, at least about 500%, at least about 600%, at least about 700%, at least about 800%, at least about 900%, at least about 1000%, at least about 1100%, at least about 1200%, at least about 1300%, at least about 1400%, at least about 1500%, at least about 1600%, at least about 1700%, at least about 1800%, or at least about 1900% greater than the  $C_{max}$  exhibited by the non-nanoparticulate formulation of the same triamcinolone, administered at the same dosage.

94. (Withdrawn) The method of claim 66, wherein the AUC of the triamcinolone composition, when assayed in the plasma of a mammalian subject following administration, is greater than the AUC for a non-nanoparticulate composition of the same triamcinolone, administered at the same dosage.

95. (Withdrawn) The method of claim 94, wherein the AUC is selected from the group consisting of at least about 25%, at least about 50%, at least about 75%, at least about 100%, at least about 125%, at least about 150%, at least about 175%, at least about 200%, at least about 225%, at least about 250%, at least about 275%, at least about 300%, at least about 350%, at least about 400%, at least about 450%, at least about 500%, at least about 550%, at least about 600%, at least about 750%, at least about 700%, at least about 750%, at least about 800%, at least about 850%, at least about 900%, at least about 950%, at least about 1000%, at least about 1050%, at least about 1100%, at least about 1150%, or at least about 1200% greater than the AUC exhibited by the non-nanoparticulate composition of the same triamcinolone, administered at the same dosage.

96. (Withdrawn) The method of claim 66, wherein when the triamcinolone composition is administered to the subject under fed conditions, the absorption levels of the at least one triamcinolone are substantially the same as compared when the composition is administered to a patient under fasting conditions.

97. (Withdrawn) The method of claim 96, wherein the difference in absorption of the triamcinolone composition of the invention, when administered in the fed versus the fasted state, is selected from the group consisting of less than about 100%, less than about 90%, less than about 80%, less than about 70%, less than about 60%, less than about 50%, less than about 40%, less than about 30%, less than about 25%, less than about 20%, less than about 15%, less than about 10%, less than about 5%, and less than about 3%.

98. (Withdrawn) The method of claim 66, wherein administration of the composition to a human in a fasted state is bioequivalent to administration of the composition to a human in a fed state.

99. (Withdrawn) The method of claim 98, wherein “bioequivalency” is established by a 90% Confidence Interval of between 0.80 and 1.25 for both  $C_{max}$  and AUC.

100. (Withdrawn) The method of claim 98, wherein “bioequivalency” is established by a 90% Confidence Interval of between 0.80 and 1.25 for AUC and a 90% Confidence Interval of between 0.70 to 1.43 for  $C_{max}$ .

101. (Withdrawn) The method of claim 66, wherein the subject is a human.

102. (Withdrawn) The method of claim 66, wherein the method is used to treat indications where glucocorticoids are typically used.

103. (Withdrawn) The method of claim 66, wherein the method is used to treat indications where steroidal anti-inflammatory agents are typically used.

104. (Withdrawn) The method of claim 66, wherein the method is used to treat indications selected from the group consisting of arthritis, skin disorders, blood disorders, kidney disorders, eye disorders, thyroid disorders, intestinal disorders, allergies, asthma, bronchial asthma, cancer, neoplastic diseases, tendinitis, allergic reactions, seasonal allergic rhinitis, perennial allergic rhinitis, oral inflammation, oral lesions, oral ulcers, bursitis, epicondylitis, keloids, endocrine disorders, herpes zoster ophthalmicus, hemolytic anemia, and acute rheumatic carditis.

105. (Withdrawn) The method of claim 104, wherein the skin disorder is selected from the group consisting of contact dermatitis, atopic dermatitis, psoriasis, eczema, and general dermatitis.

106. (Withdrawn) The method of claim 104, wherein the arthritic condition is selected from the group consisting of osteoarthritis, acute nonspecific osteoarthritis, posttraumatic osteoarthritis, and rheumatoid arthritis.

107. (Withdrawn) The method of claim 104, wherein the intestinal disorder is selected from the group consisting of ulcerative colitis, colitis, gastroenteritis, irritable bowel disorder, and Crohn's disease.

108. (Withdrawn) The method of claim 66, wherein the method is used to treat indications selected from the group consisting of asthma, seasonal allergic rhinitis, and perennial allergic rhinitis.

APPENDIX B: RELATED PROCEEDINGS

No related proceedings are pending.